

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE

In re Application of:

Wolfgang STAEHLE et al.

Group Art Unit 1626

Serial No.: 10/573,176

Examiner: Alicia L. Otton

Filed: March 23, 2006

Title: 1,3-BENZOXAZOLYL DERIVATIVES AS KINASE INHIBITORS

PETITION OF THE RESTRICTION REQUIREMENT UNDER 37 C.F.R. §1.181

TECHNOLOGY CENTER 1600

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

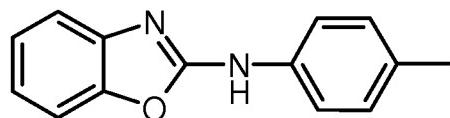
This is a petition requesting the Commissioner, through the Honorable Group Director, to reverse the Examiner's decision in maintaining the Restriction Requirement. Specifically, applicants request that examination be performed on **the entire scope of compound claim 1** (i.e., Groups I and II), and that the methods of using the compounds (Groups III and IV) be examined with the compound claims.

Statement of Facts

In the Office Action issued December 9, 2008, the Examiner presented a Restriction Requirement wherein applicants' compound genus was divided into 2 Groups, depending on the definition of group Y of in Formula I. In Group I, the subject matter was directed to compounds of Formula I wherein Y is phenyl or pyridyl. In Group II, the subject matter was directed to compounds of Formula I wherein Y is other than either phenyl or pyridyl.

The Restriction Requirement included two other Groups, i.e., Group III directed to methods of using the compounds of Group I, and Group IV directed to methods of using the compounds of Group II. Further, the Examiner made an Election of Species Requirement with regards to the election of a specific species of the compound genus.

The Restriction asserted that the claims lacked unity because under PCT Rule 13.2 they lack the same or corresponding special technical feature. Specifically, the Examiner argues that the “core structure” of the compounds encompassed by the claims lacked a special technical feature. The Examiner further argued that the “core structure” of the compounds was of the following structure and that this structure “can be found in numerous patents and papers”:



The Examiner cited US 2003/0225131 as an example (specifically compound #55).

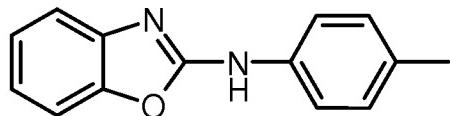
In response to this Restriction Requirement, applicants elected Group I, i.e., wherein Y is phenyl or pyridyl, which included claims 1-11 and 30-38 directed to compounds, processes of making such compounds, and kits containing such compounds. In response to the Election of Species, applicants hereby elected the compound (5-Chloro-7-nitrobenzoxazol-2-yl)-[4-(pyridin-4-ylsulfanyl)phenyl]amine. See Reply filed February 9, 2009

Applicants traversed the Restriction Requirement. Applicants argued that under section (d) of Annex B (Unity of Invention) of the Administrative Instruction under the PCT there are three particular situations for determining unity of invention under Rule 13.2. These three particular situations are discussed in sections (e), (f), and (g) of Annex B. Section (f) discusses the principles for interpreting unity of invention under Markush practice, such as applicants' compound claims.

Applicants' argued that Section (f) of Annex B states that the requirements for unity under PCT Rule 13.2 for a Markush grouping will be met if the alternatives of the grouping are of “a similar nature.” Further, as indicated in section (f)(i), the alternatives will be regarded as **fulfilling the criteria of being of a similar nature if the alternatives have a common property/activity and have a common significant structural element (i.e., a common**

chemical structure which occupies a large portion of their structure).

Applicants then argued that, in the instant case, the compounds share the common activity of modulating signal transduction by kinases, and the compounds exhibit a common significant structural element, namely:



Therefore, applicants asserted that the claimed Markush grouping satisfied the requirement of section (f) of Annex B and, thus, satisfied the requirements for unity of invention under PCT Rule 13.2.

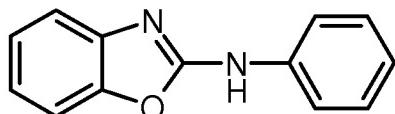
Applicants also argued that 35 USC §121 does not permit restriction within a single claim as indicated by the court in *In re Weber et al.*, 198 USPQ 328 (1978). The effect of restriction within a single claim is the same as a rejection. 35 USC §121 does not give the Commissioner authority to require that a single claim "be divided up and presented in several applications" and thus deny the Applicant the right to have that single claim considered on its merits.

As noted in MPEP §803.02, which describes the criteria for restriction practice relating to Markush-type claims, since the decisions in *In re Weber* and *In re Haas*, "it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention." Thereafter, the MPEP cites *In re Harnish*, 206 USPQ 300 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ2d (Bd. Pat. App. & Int. 1984). These two cases both deal with improper Markush rejections. Thus, in the case of Markush claims, refusal by the Office to examine that which the applicants regard as their invention must be a refusal based on an improper Markush rejection. For the reasons discussed above, applicants Markush grouping is proper.

The Restriction Requirement was also traversed with respect to the Restriction between Groups I/II and Groups III/IV. The Restriction did not present any rationale as to why the methods of using the compounds recited in the claims of Groups III/IV were being restricted from the compounds of Groups I/II. Moreover, applicants argued that section (e)(i) of Annex B

states that an independent product claim, an independent process claim specially adapted to manufacture the product, and an independent claim for use of the product is a permissible combination and will be construed as in compliance with the unity of invention requirement under PCT Rule 13.2.

In the Office Action issued February 20, 2009, the Examiner argued that the non-variable core of the claimed compounds was of the following structure:



The Examiner again argued that this core structure did not make a contribution over the prior art, citing US 2003/0225131 and Example 10 of WO 02/07690, and therefore lacked unity under 37 CFR 1.475. As a result, the Examiner made the Restriction Requirement Final. The Examiner did not indicate why applicants' Markush grouping did not satisfy the requirements set forth in section (f) of Annex B (Unity of Invention) of the Administrative Instruction under the PCT and thus the requirements for unity under PCT Rule 13.2.

With regards to the Restriction between Groups I/II and Groups III/IV, the Examiner cited the five combinations defined in 37 CFR 1.475(b), and then further stated that "according to 37 CFR 1.475(c): if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph 37 CFR 1.475(b), unity of invention **might** not exist." (emphasis added). However, the Examiner did not present reasons as to why in the present case unity of invention did not exist under 37 CFR 1.475(c). Instead, the Examiner stated that the reason for the Restriction between Groups I/II and Groups III/IV "lies in the lack of unity of invention according to PCT Rule 13.1, which is a result of the failure of the invariable core of the instantly claimed compounds to make a contribution over the prior art." See page 7 of the February 20, 2009 Office Action.

Regarding applicants arguments concerning 35 USC 121, the Examiner stated that the common core structure of the compounds of the Markush group lacked unity of invention because it did not make a contribution over the art.

In the Reply filed July 20, 2009, applicants reiterated their traverse of the Restriction, arguing again that the Markush grouping satisfied PCT Rule 13.2 because, in accordance with the requirements of section (f) of Annex B, the alternatives of the Markush grouping shared a common property or activity, and shared a significant common structural element. Applicants also argued that neither section (f) of Annex B, nor 37 CFR 1.475 required that a significant common structural element make a contribution over the prior art. Additionally, concerning 35 USC 121, applicants argued that requiring a common core structure that makes a contribution over the prior art is not part of the test for a proper Markush group as set forth in *In re Harnish*, 206 USPQ 300 (CCPA 1980).

Thereafter, in the Office Action issued December 7, 2009, the Examiner again responded to applicants' arguments regarding the Restriction. Specifically, the Examiner argued that the common structural element was not significant because, due to the variable groups, the claimed compounds can contain ring structures in addition to the common structural element.

In the Reply filed February 12, 2010, applicants responded to the Examiner's argument concerning the size of the common structural element. Applicants argued that the Examiner's assertion did not abrogate the fact that the common core structure with its three rings and amino group was a large part of the compound structure. Applicants argued that section (f) of Annex B does not require "large" to mean a majority or most of the structure. One skilled in the art would recognize that for any of the compounds within the claimed genus, the common core structure identified by applicants is a large part of their structure.

In response to applicants' arguments, in the Office Action issued April 12, 2010 the Examiner stated that the Restriction had been made final, and the Examiner's reasons for maintaining the Restriction had been made of record.

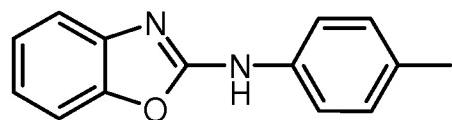
Summary of Argument in Support of Reversal of Denial to Extend the Search

Applicants respectfully submit that their Markush compound claims possesses unity of invention under PCT Rule 13.2 because the claims satisfy the requirements of section (f) of Annex B (Unity of Invention) of the Administrative Instruction under the PCT.

Section (d) of Annex B states that there are three particular situations for determining unity of invention under Rule 13.2. The principles for interpreting these three particular situations are discussed in sections (e), (f), and (g) of Annex B. **Further, section (d) of Annex B makes it clear that the principles set forth in the discussion in sections (e), (f), and (g) are to be understood as an interpretation of the requirements under PCT Rule 13.2.**

Section (f) of Annex B deals with one of these three specific situation, namely “Markush” practice. The principles for interpreting unity of invention under Markush practice are discussed in Section (f) of Annex B states that the requirements for unity under PCT Rule 13.2 for a Markush grouping will be met if the alternatives of the grouping are of “a similar nature.” Further, as indicated in section (f)(i), the alternatives will be regarded as fulfilling the criteria of being of a similar nature if the alternatives have a common property/activity and have a common significant structural element (i.e., a common chemical structure which occupies a large portion of their structure).

In the instant case, the compounds share the common activity of modulating signal transduction by kinases. In addition, the compounds exhibit a common significant structural element, namely:



It is noted that section (f) does not require that common significant structural element represent a majority of the overall structure of the compounds of the Markush group. Also, contrary to the Examiner’s arguments, section (f) does not require that common significant structural element define a contribution over the prior art.

The claimed Markush grouping satisfies the requirement of section (f) of Annex B. Therefore, the claimed Markush grouping meets the requirements for unity of invention under PCT Rule 13.2, as interpreted in sections (d) and (e) of Annex B.

With respect to Groups III and IV, the claims in these groups are directed to methods of using the compounds of the Markush group. The application also contains claims directed to methods of manufacturing the compounds of the Markush group.

Another of the three particular situations for determining unity of invention under Rule 13.2 mentioned in section (d) of Annex B concerns certain combination of claims. These are described in section (e). Section (e)(i) of Annex B states that an independent product claim, an independent process claim specially adapted to manufacture the product, and an independent claim for use of the product is a permissible combination and will be construed as in compliance with the unity of invention requirement under PCT Rule 13.2. Claims within Groups III/IV, in conjunction with claims in Groups I/II, make up such a combination. Thus, for Groups I-IV of the Restriction unity of invention exists under PCT Rule 13.2, as interpreted in sections (d) and (e) of Annex B.

The Examiner's assertion that Restriction between Groups I/II and Groups III/IV is a result of the failure of the invariable core of to make a contribution over the prior art does not address the analysis sections (d) and (e) of Annex B, which provides interpretation of PCT Rule 13.2 in the matter of certain combination of claims, such as the combination presented in the instant application.

Applicants note that Annex B was superseded by the PCT International Search and Preliminary Examination Guidelines issued in 2004. However, the ISPE guidelines on unity of invention are very similar to the prior Annex B. See sections 10.11-10.17 of the PCT International Search and Preliminary Examination Guidelines.

Also, with regards to restriction within a Markush claims, it is noted that 35 USC §121 does not permit restriction within a single claim as clearly indicated by the court in *In re Weber et al.*, 198 USPQ 328 (1978).

As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of

applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits.

It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to *restrict* an *application* to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to *reject* a particular claim on that same basis. [Weber at 331-332]

The effect of restriction within a single claim is the same as a rejection. 35 USC §121 does not give the Commissioner authority to require that a single claim "be divided up and presented in several applications" and thus deny the applicant the right to have that single claim considered on its merits. This is exactly the action that the Court in *Weber* stated was not permitted under 35 USC §121. Such action by an Examiner would violate "the basic right of the Applicant to claim his invention as he chooses." [Weber at 332]

Applicants' claims recite a proper Markush grouping. See *In re Harnisch*, 206 USPQ 300 (CCPA 1980). As discussed above, the compounds of applicants' claimed genus share a common property and exhibit a significant unchanging core structure.

Conclusion

For the forgoing reasons, Applicants request reversal of the Examiner's decision to maintain the Restriction Requirement set forth in the December 9, 2008, and that examination be extended to the full scope of all pending claims.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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Attorney Docket No.: **MERCK-3155**

Date: December 9, 2010